K130702

Airsonett AIRSONETT AB, Metallgatan, SE-262 72 Ängelholm, Sweden

510(k) SUMMARY

JUL 2 3 2013

Submitter: Airsonett AB
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Submission Date: March 15, 2013

Device Name and Classification: Airsonett, version AIR-4, Class II
21 CFR 880.5045
Product Code: FRF

Equivalent Device Identification: Airsonett Airshower Air-3, K081062, BREATHE EASY (Models AD and CD) by RespirAid Ltd (K981841)

Device Description:

Airsonett is based on the Temperature controlled Laminar Airflow (TLA) technology. The air from the room enters the Airsonett and passes a filter that captures allergens and other particles. The filtered air is cooled to slightly below the ambient room temperature and is supplied with a low velocity from the air supply nozzle. Since the filtered air is slightly cooler, and therefore heavier than the surrounding air, the filtered air will descend slowly from the air supply nozzle by means of gravity in a laminar manner (non-turbulent). This descending colder air counteracts the body convection, displaces the allergen load in the breathing zone and thus dramatically reduces the level of inhalant allergens for the patient all through the night.

Air is drawn in through the air intake at the floor level and through the **HEPA filter**. A silent **Blower** (fan) brings airflow through the filter. The air is directed through the **Cooler/Heater** and divided into a cool respectively warm air flow. The cool air flow is directed through the **Air guidance arm** (neck) and out through the **Airshower** (Air Supply Nozzle). The Airshower can be altered in height, by adding/removing and combining the neck parts, to adapt to different types of environments. The warm air flow is directed to the **Warm air outlet**. On its way to the outlet the air flow passes the electronics and transports away the extra heat produced by the electronics.

Airsonett is based on a microprocessor controlled supervisory system. This system controls the device behaviour by measuring temperatures, controlling thermoelectric modules and fan unit, monitoring user interaction as well as management of internal timers to keep track of the total ontime for the system and time since last filter change. The control functions (Front Panel Board) and power distribution function (Power Electronics Board) are allocated on two separate circuit boards,

Intended Use: The Airsonett AIR-4 is a Mobile Air Cleaner intended to be used to remove particles from the air for medical purposes. The device is intended for home use only.

Comparison Table:

Element of Comparison	**Subject Device**	**Claimed SE Device**
Product	Airsonett AIR-4	Airsonett Airshower Air-3, (510(k) Number K081062)
Manufacturer	Airsonett AB	Airsonett AB
Type of Medical Re-circulating Air Cleaner	Mobile Air Filtration system	Mobile Air Filtration system
Intended use	The Airsonett AIR-4 is a Mobile Air Cleaner intended to be used to remove particles from the air for medical purposes. The device is intended for home use only.	The Airsonett Airshower Air 3 is a Mobile Air Cleaner intended to be used to remove particles from the air for medical purposes. The device is intended for home use only.
Type of device	Over the counter use	Over the counter use
Labeling	**Airsonett AIR-4**	**Airsonett Airshower Air-3**
Product Description	Housing Unit	Housing Unit
	Air Inlet and Treated Air Outlet	Air Inlet and Treated Air Outlet
	Blower	Blower
	HEPA filter	HEPA filter
	Air Warming Unit	Air Warming Unit
	Air Cooling Unit	Air Cooling Unit
	Adjustable Air Guidance Arm	Adjustable Air Guidance Arm
	Control Panel	Control Panel

Element of Comparison	Subject Device	Claimed SE Device
	Airsonett Airshower makes use of the Airshower characteristics and cools the air outflow; thereby using thermal stratification for guiding the air to a patient's breathing zone.	Airsonett Airshower makes use of the Airshower characteristics and cools the air outflow; thereby using thermal stratification for guiding the air to a patient's breathing zone.
Power Requirements	115-230V~ (60-50Hz), 1.7-1.0A	115 V-230V~ (60-50Hz), 1.7-1.0 A
Standard	IEC 60601-1	IEC 60601-1
Air Flow	Airflow in clean air zone (cool side): At least 120 m^3/h Airflow warm side: Approx. 80 m^3/h Total airflow: Approx. 200 m^3/h	Airflow in clean air zone (cool side): Approx. 150 m^3/h Airflow warm side: Approx. 80 m^3/h Total airflow: Approx. 230 m^3/h
Air Quality in treated air envelope (referred as clean zone in Appendix 1.2)	Filtration efficiency 99.5% of particles Ø ≥0.5µm which is equivalent to -Class 1000 according to FED STD 209E and -Class 6 according to ISO 14644-1 in environments of ≤200 000particles/ft^3	Class 100-1000 according to FED STD 209E
Rate of Air Changed	At least 435 changes per hour	~1500 changes per hour
Sound Level	≤38 dB(A)	~38 dB(A)

Element of Comparison	Subject Device	Claimed SE Device	Previous 510(k) SE Device for Airsonett Airshower Air-3
Manufacturer	Airsonett AB	Airsonett AB	RespirAid Ltd.
Air Flow	Airflow in clean air zone (cool side): At least 120 m^3/h Airflow warm side: Approx. 80 m^3/h Total airflow: Approx. 200 m^3/h	Airflow in clean air zone (cool side): Approx. 150 m^3/h Airflow warm side: Approx. 80 m^3/h Total airflow: Approx. 230 m^3/h	20-40 m^3/h
Rate of Air Changed	At least 435 changes per hour	~1500 changes per hour	400-600 changes per hour

Summary of Testing:

Listing of standards applied

- IEC 60601-1, Second edition, 1988 with Amendment 1, 1991 and Amendment 2, 1995, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

- IEC 60601-1-2, Third edition, 2007, Medical Electrical Equipment – Part 1-2: General Requirements for basic safety and essential performance; Electromagnetic Compatibility – Requirements and tests.

Performance Tests

Study endpoint	Description of Test	Acceptance criteria	Conclusion
Air quality in treated air envelope (clean zone)	Efficiency test results of filter.	Filter Filtration efficiency ≥99.5% of particles with size Ø≥0.5µm	Conforms with filtration efficiency ≥99.5%.
	Particle cleanliness of clean zone of Airsonett AIR-4. Test method: Laser counter of particles Ø≥0.5µm/ft^3 air flow over 1 minute.	Clean zone Filtration efficiency ≥99.5% of particles with size Ø≥0.5µm which is equivalent to -Class 1000 according to FED STD 209E and - Class 6 according to ISO 14644-1 in environments of ≤200 000particles/ft^3.	Conforms with filtration efficiency ≥99.5%. ⇨ Class 1000 according to FED STD 209E and Class 6 according to ISO 14644-1 in environments of ≤200 000particles/ft^3. AIR-4 is equivalent or better than previous version AIR-3, with regard to Air quality in treated air envelope (clean zone).
	Particle cleanliness of clean zone of Airsonett AIR-4.	Stability of the clean zone shall be preserved. Filter efficiency shall be preserved.	The stability of the clean zone is preserved and the filter does not deteriorate on efficiency over a normal working life.
Temperature difference between supply air and ambient air	The cooler/heater unit has been individually tested against temperature sensors to calibrate and verify the temperature difference between supply air and ambient air.	Temperature difference between supply air and ambient air: ≥0.75°C (1.35 degrees F).	Conforms with temperature difference between supply air and ambient air: ≥0.75°C (1.35 degrees F).

Conclusion: Airsonett AIR-4 is substantially equivalent to Airsonett Air-3 and Breathe Easy regarding technology, intended use and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 23, 2013

Airsonett, AB
C/O Ms. Constance G. Bundy
C.G. Bundy Associates, Incorporated
435 Rice Creek Terrace, North East
FRIDLEY MN 55432

Re: K130702
Trade/Device Name: Airsonett, Version AIR-4
Regulation Number: 21 CFR 880.5045
Regulation Name: Medical Recirculating Air Cleaner
Regulatory Class: II
Product Code: FRF
Dated: July 1, 2013
Received: July 2, 2013

Dear Ms. Bundy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): k130702

Device Name: Airsonett, version AIR-4

Indications For Use:

The Airsonett AIR-4 is a Mobile Air Cleaner intended to be used to remove particles from the air for medical purposes. The device is intended for home use only.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie
2013.07.23 14:26:39 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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